REMARKS/ARGUMENTS

Election/Restrictions

The Examiner noted that claims 2, 8, 15, 24-75, and 78-105 are withdrawn from further consideration as being drawn to a nonelected species.

RESPONSE

In response, Applicant has amended the listing of claims to properly indicate the withdrawn claims.

Claim Rejections – 35 USC §112

The Examiner rejected claim 3 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 3 contains the trademark "Elgiloy." Also, claim 3 should have the work "body" inserted after the word "stent" for clarification of the part that is formed of the shape of the memory metal.

RESPONSE

In response, Applicant has amended claim 3 as follows: (1) in accordance with MPEP §608.01(v), each letter of the trademark "Elgiloy" has been capitalized and (2) the word "body" has been inserted after the word "stent."

Claim Rejections – 35 USC §102

The Examiner rejected claims 76 and 77 under 35 USC §102 as being anticipated by U.S. Patent No. 6,517,575 issued to Yang et al.

According to the Examiner, Yang discloses a self-expanding stent that is in the form of a rolled sheet. The rolled sheet has many layers, including a layer of expandable filler material. Yang explains that the expandable filler material swells upon absorbing water when placed in a body lumen (column 2, lines 45-50 and column 4, lines 60-65).

RESPONSE

The Yang patent cited by the Examiner was issued for Multilayer Liquid Absorption and Deformation Devices. As discussed below, the present invention differs from the Yang patent in several respects.

In Yang, the purpose of the water absorbing material 12 is for deployment only (column 1, lines 63 through column 2, line 14 and Figure 4). In contract, the device of the present invention is partially deployed by use of a balloon, and additional expansion of the stent occurs as fluid is absorbed from the bloodstream over time (page 4, lines 12-13).

The Yang patent states that the invention "is analogous in a general way to a bimetal" (column 1, lines 53-54). In a bimetal structure each layer expands differently so as to deform the combined structure. Therefore, all that occurs with the Yang device is deformation or expansion of the structure, not occlusion of the vessel.

"A previous patent . . . anticipates a purported invention only where, except for insubstantial differences, it contains all of the same elements operating in the same fashion to perform an identical function." *National Business Systems, Inc. v. Am International, Inc.*, 743 F.2d 1227, 1235 (7th Cir. 1984) (quoting *Popeil Bros., Inc. v. Schick Electric, Inc.*, 494 F.2d 162, 164 (7th Cir. 1974)). As discussed, the Yang patent

does not operate in the same fashion as the present invention to perform an identical function.

The materials identified in the Yang patent would be classified as hydrophilic (column 2, lines 50-57). The absorbable materials that are identified in the application for the present invention are not listed in the Yang patent, i.e. casein and superabsorbers. The moisture absorption of the Yang hydrophilic materials is far less than casein or a superabsorber. As a result, the Yang hydrophilic materials could not be used for occlusion, only deployment. It should be noted that the benefits to the patient from slow deployment are not discussed.

The Yang device includes two components that could be combined with a stent (column 1, line 63 through column 2, line 14). The absorbable material of the device of the present invention is completely different and with different characteristics than those described of the Yang patent. The absorbable material is the device of the present invention is then combined with a stent. All three components of the device of the present invention are then encapsulated in a barrier material, which is used to control the rate of occlusion. The Yang device could not be used for occlusion, regardless of the amount of absorbable material that was used, because the materials do not expand as does casein or a superabsorber.

Further, in the device of the present invention, the absorbable material is bonded to a thin foil. The main purpose of the foil is to inhibit the absorbable material from expanding into the openings of the stent. The foil slides across the open surface of the stent, expanding the stent and occluding the vessel. If the absorbable material could enter the openings in the stent, (a) expansion of the stent could be irregular, non-cylindrical, or

(b) portions of the absorbable material could break away, or (c) plaque could be dislodged from the vessel, or (d) the vessel could be damaged.

Claim Rejections – 35 USC §103

The Examiner rejected claims 1, 4, 5, 9-14, 16, and 19-23 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,458,152 issued to Khosravi et al. in view of Yang.

According to the Examiner, Khosravi discloses a rolled sheet self-expanding stent that includes layers of different materials. One layer, or "stent body," is formed from a shape memory metal (column 6, lines 40-45). A polymeric layer is disposed on the interior of the stent body and can be in the form of several layers (column 3, lines 35-45). An additional polymer layer can be disposed on the exterior of the stent to form a "barrier film," and it can be porous (column 5, lines 35-50). An alternate barrier film encapsulating the stent it disclosed (column 7, line 61 through column 8, line 5). The stent can also include a coating of heparin (column 8m lines 63-65). A balloon catheter can be used for implantation (column 9, line 36 and Figure 5B).

According to the Examiner, Khosravi fails to include an expandable filler material, but does state that the inner polymer layer can be formed as several layers (column 3, lines 35-45). Khosravi also requires a balloon catheter for aiding in the expansion of the prosthesis. As explained above, Yang also discloses a rolled sheet self-expanding vascular prosthesis. Yang teaches that this type of prosthesis should include an expandable filler material bonded to another thin sheet. The expandable material aids in the self-expansion of the stent, as it causes the sheet to unroll and expand as the

material swells when in contact with water in the body lumen. Yang also explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3). These statements provide motivation to combine the Yang and Khosravi devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the multilayered polymer portion of the Khosravi stent as an expandable filler material bonded to a thin sheet, as Yang teaches that this combination of materials aids in the self expansion of a rolled sheet stent. The expanding material may be capable of replacing the use of a balloon catheter.

According to the Examiner, Yang also states that the expandable layer may be biodegradable and gives many examples of materials that can form the expandable polymer layer in column 3. The expandable layer (20) is disposed on a thin sheet of material that can be polymeric or metallic (10) (column 2, lines 55-60). Yang explains that other types of payers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3).

According to the Examiner, claims 10 and 13 only include limitations pertaining to the method by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious and is not governed by whether the process by which it is made is patentable. Therefore, the limitations of claims 10 and 13 were not given patentable weight.

According to the Examiner, claims 19-21 only pertain to the intended use of the device. The only requirement here is that the prior art stent be capable of performing these functions. Since the Yang stent is capable of being used with another stent and in procedures pertaining to animals or humans, it meets the limitations of claims 19-21.

RESPONSE

The Khosravi patent cited by the Examiner was issued for a Coiled Sheet Graft for Single and Bifurcated Lumens and Methods of Making and Use. As discussed below, the present invention differs from the Khosravi patent in several respects.

The usage of the Khosravi device usage is different than the usage of the device of the present invention. A stent graft is used to repair damage, such as a hole, in an artery or major vessel. The "graft" material replaces the vessel wall, and the stent provides structural integrity for the graft. The examples offered in the patent include a hole in the artery caused by an aneurysm or a gunshot (column 3, line 15 and column 2, line 51).

The two-layered Khosravi device described includes a "graft" material to patch the hole, and a metal layer, the two being spirally wound (column 5, lines 27-29). The metal layer in Khosravi is functioning to provide structural integrity to the graft. In the device of the present invention, there is a separate stent, and the spirally wound element is the foil, with the primary purpose to inhibit the absorbable material from entering the openings of the stent during occlusion.

The metal used for the metal layer in Khosravi is a "shape-memory" alloy (column 3, line 49), which has been selected because it will expand partially, due to the "shape-memory" properties. However, a mechanical expander is still required for complete deployment (claims 2 and 5, and Figure 5B).

The Khosravi patent makes no reference to any absorbable materials.

The device of the present invention is completely deployed by a balloon or other mechanical means. The foil in the device of the present invention does not truly expand, but follows the expansion of the absorbable material that is attached to the foil.

In addition, the arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

With respect to claims 10 and 13, Applicant respectfully respects that claim 10 be included within Invention #2 and that claim 13 be included within Invention #4.

Claim Rejections – 35 USC §103

The Examiner rejected claim 3 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,042,605 issued to Martin et al.

According to the Examiner, the modified Khosravi device fails to form the stent body from a cobalt-chrome alloy or Elgiloy. Khosravi does state that the stent body can be formed of nitinol or stainless steel (column 6, lines 41-45). Martin discloses a stent body disposed over a polymer graft. Martin teaches that Elgiloy is a suitable material to use as a substitute for nitinol, as it is highly resilient (column 11, lines 5-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

substitute Elgiloy for nitinol for the material of the stent body of the modified Khosravi stent, as Martin teaches that Elgiloy has good mechanical properties for forming stents.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Martin patent cited by the Examiner was issued for a Kink Resistant Stent-Graft. As discussed below, the present invention differs from the Martin patent in several respects.

Like Khosravi, the Martin device is also a stent graft. There are three components in the Martin device: a stent formed of thin wire, a graft material, and a material connecting the two, i.e. the helically wound "ribbon" (column 2, line 51). The graft material may be "any material which is suitable for use as a graft in the chosen body lumen" (column 12, lines 23-24). The ribbon is the only wound component, although the wire mesh of the stent does follow a helical pattern, and could also be considered as helically wound (column 9, line 67). However, wound implies a manufacturing process,

and although the final appearance of the mesh is helical, a weaving process is used instead of a winding process to produce it.

Further, the connecting ribbon of Martin is helically wound, and therefore the winds do not overlap each other. Instead, the winds are adjacent to each other with a space in between. The space is intentional and provides flexibility to the stent graft to facilitate deployment at the target site.

In contrast, the wound components in the device of the present invention are "spirally" wound to allow each layer of the wound assembly to slide freely as the absorbable material expands to occlude the vessel (Figure 1(a) and 2(b)).

Claim Rejections – 35 USC §103

The Examiner rejected claim 6 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 6,428,571 issued to Lentz et al.

According to the Examiner, as explained above, Yang discloses many different materials for forming the expandable layer in column 7. Among those materials are gelatin, collagen, albumin, and starch. Lentz teaches that casein is another natural material equivalent to gelatin, collagen, albumin, and starch for forming expandable polymer layers (column 8, lines 38-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include casein in the expandable filler material of the modified Khosravi device, as Lentz teaches that casein in simply an alternate natural material for forming expandable polymer layers.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Lentz patent cited by the Examiner was issued for Self-Sealing PTFE Vascular Graft and Manufacturing Methods. As discussed below, the present invention differs from the Lentz patent in several respects.

The Lentz device is comprised of two layers, both of PTFE. One is more porous to allow natural tissue growth, and the other provides radial strength and resistance to axial tear (column 3, lines 4-7). The two distinct layers are actually extruded tubes of PTFE. The purpose of this invention is to support hemodialysis, which typically involves puncturing the graft to withdraw blood (column 6, lines 56-64). The need they have solved is to create a self-sealing graft.

Although one of the claims of the patent application of the present invention identified PTFE as a barrier material (withdrawn claim 8), polypropylene was selected as the barrier film of the elected embodiment (claim 7). In the device of the present

invention, the barrier material completely encapsulates the stent and spirally wound components, and is used to control the rate of moisture absorption and thereby control the rate of occlusion. This is accomplished by dictating the pore density and pore size of the barrier material. Lentz device is not encapsulated in a barrier material. Therefore, Lentz's use of PTFE is different than in the device of the present invention.

Claim Rejections – 35 USC §103

The Examiner rejected claim 7 under 35 USC §103 as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of U.S. Patent No. 5,824,046 issued to Smith et al.

According to the Examiner, Khosravi states that the outer polymer layer, or "barrier film," can for formed of graft materials, such as PTFE, polyester, or urethane (column 7, lines 11 and 64). Smith discloses a stent with a polymeric outer layer. Smith teaches that polypropylene is a suitable substitute for PTFE, polyurethane, and polyester for forming the barrier film (column 7, lines 32-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier film of the modified Khosravi device of polypropylene, as Smith teaches that this material is suitable for forming a barrier film for a stent.

RESPONSE

The arguments in response to the Examiner's 103 rejection based on the Khosravi patent are hereby incorporated by reference including, but not limited to, the following: (1) the usage of the Khosravi device differs from the usage of the device of the present

invention; (2) the Khosravi device requires a mechanical expander for complete deployment; and (3) the Khosravi patent makes no mention of absorbable materials.

The arguments in response to the Examiner's 102 rejection based on the Yang patent are hereby incorporated by reference including, but not limited to, the following: (1) the purpose of the water absorbing material in Yang is for deployment only; (2) occlusion of the vessel does not occur with the Yang device; and (3) the moisture absorption of the materials mentioned in Yang is far less than casein or a superabsorber.

The Smith patent cited by the Examiner was issued for a Covered Stent. As discussed below, the present invention differs from the Smith patent in several respects.

The Smith invention utilizes a PTFE barrier material in combination with a stent (column 5, lines 20-22). However, the sole purpose of the barrier is to inhibit particles, such as plaque, on the wall of the vessel from traveling through the openings of the stent and causing blockage, restenosis, or other issues at the target site or elsewhere in the vascular system (column 1, lines 44-52). The barrier as defined is only on the outer surface of the stent, somewhat like a sleeve.

In the device of the present invention, the barrier completely encapsulates the stent and spirally wound components for the primary purpose of controlling the rate of moisture absorption and thereby controlling the rate of occlusion. This is accomplished by dictating the pore density and pore size of the barrier material. Additionally, the barrier of the present invention also acts to prevent bacteria ingress, since the size of bacteria is larger than the pore size used in the barrier. Also, by encapsulating the entire device, any portion of the absorbable material that breaks away during deployment or expansion is captured and can not migrate in the bloodstream to cause a blockage

elsewhere. In the device of the present invention, the preferred barrier is actually polypropelene (PP), because it is more hydrophilic than PTFE, and it can be heat-sealed. PTFE could be used in place of PP in the device of the present invention, but the PTFE would need to be modified through radiation grafting or some other means to improve moisture absorption (hydrophilic tendency).

CONCLUSION

Reconsideration and further examination is respectfully requested.

A one month extension of time is required to file this response, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely. Please charge Deposit Account Number 120115 in the amount of $60 for this extension. Further, the Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 120115.

Applicant has made a diligent effort to place the new claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Melissa Patangia, Applicant's Attorney at (617) 720-0091 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

3/14/05 Melissa Patangia

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